The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Radiation Control Program
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January 12, 2001

NOTICE

REGULATORY POLICY ANNOUNCEMENT

Effective immediately, the Department of Public Health, Radiation Control Program (the Agency), has adopted the following policy concerning 105 CMR 120.543, Use of Sources for Brachytherapy:

> **In place of the requirement in 105 CMR 120.543(A), (B), (C), (D), (E), (F), and (G), licensees who are currently authorized under 105 CMR 120.543 may use brachytherapy sources for therapeutic medical use in accordance with the provisions in the Sealed Source and Device Registry; or in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA, provided the sealed sources or devices have been initially manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to 105 CMR 120.000, or the equivalent regulations of another Agreement State, a Licensing State, or the NRC. Licensees currently authorized under 105 CMR 120.543 who wish to use such brachytherapy sources for treatments, as authorized above, do not need to file an amendment request with the Agency to begin performing these treatments; however, licensees should document the review and approval by the Radiation Safety Committee and notify the Agency within 30 days after any such approval.**

The policy position mirrors the new requirements set forth by the NRC in 10 CFR 35.400.

FOR THE COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF PUBLIC HEALTH
RADIATION CONTROL PROGRAM

Date_____ By ORIGINAL SIGNED BY ROBERT HALLISEY 1/12/2001
Robert M. Hallisey, Director